



PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Little, et al.	Art Unit:	3731
Serial No.:	09/975,427	Examiner:	Nguyen
Filed:	October 10, 2001		
Docket No.:	S145-USA		
For:	Medical Tack with Variable Effective Length		

March 8, 2004

BRIEF FOR THE APPELLANT

I. REAL PARTY IN INTEREST

The real party in interest in this Appeal is Second Sight Medical Products, Inc., having an office at 12744 San Fernando Road, Sylmar CA 91342, by virtue of an Assignment from the inventors, recorded December 26, 2001, at Reel 012255, Frames 0466.

II. RELATED APPEALS AND INTERFERENCES

There are no other appeals or interferences known to the patent owner, the patent owner's legal representative or the inventor which will directly affect or be directly affected by or have a bearing on the Board of Patent Appeals and Interferences in this pending Appeal to the present knowledge of the undersigned.

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02 FC:2402 250.00 DA

III. STATUS OF CLAIMS

The present application was filed on October 10, 2001. 22 original claims were presented, and no amendment has been made to the claims. Claims 1-22 stand rejected. No claim has been allowed. Claims 1 – 6 and 10 stand rejected under 35 USC 102 as anticipated by US Patent 5,471,268 (Schutz). Claims 11, 12, and 14 stand rejected under 35 USC 102 as anticipated by US Patent 6,165,192 (Greenberg). Claim 7 stands rejected under 35 USC 103(a) as unpatentable over Schutz. Claims 6 and 9 stand rejected under 35 USC 103(a) as unpatentable over Schutz in view of US Patent 5,364,365 (Wortrich).

What Appellant believes to be a true copy of the claims presently under appeal appears in Appendix A attached to the end of this Brief.

IV. STATUS OF AMENDMENTS

The Examiner has presented two Office Actions in the present case. No amendment has been made to the claims as a result of those office actions. Hence, there is no outstanding issue with respect to entry of amendments.

V. SUMMARY OF THE INVENTION

The present invention is a medical tack. The tack of the present invention includes attachment points at each end where at least one of the attachment points is moveable, varying the effective length of the tack. A preferred embodiment includes a barb near its point to attach to the back side of the selected tissue and an adjustable base, preferably a spring loaded adjustable base. The tack exerts controlled force on a medical device, or directly to tissue, provided that the tissue thickness is within a selected range.

VI. ISSUES ON APPEAL

The statutory provision of 35 U.S.C. §102 and 103(a) forms the basis for the rejection of claims 1-22, all of the claims on appeal. This rejection is based upon references, US Patent 5,471,268 (Schutz), US Patent 6,165,192 (Greenberg), and US Patent 5,364,365 (Worrich).

The Examiner's position is that the present invention is anticipated by, or obvious in view of, the cited prior art. Schutz and Greenberg disclosed spring loaded tack inserters. Worrick is a spring loaded cover for a surgical blade. The present invention is a medical tack. Several means are disclosed and claimed, one of which is a spring.

It appears that the sole issue to be decided in this appeal is whether or not using a spring as a driving force for a tack inserter can be said to properly render the appealed claims to a spring used to vary the effective length of a tack obvious within the meaning of 35 U.S.C. §103(a).

VII. ARGUMENTS

Schutz discloses tacking nails and a tacking device (a tool to insert the tacking nails). This tacking device (figure 1) does indeed include a spring. However, the tacking nail itself (figure 2) does not. The spring in the tacking device serves to force a tacking nail into tissue at the time of implant. It does not affect the effective length of the tacking nail, nor does it remain with the tacking nail once implanted. The tacking nail disclosed in figure 2 of Schutz is typical of the prior art and in no way discloses the present invention. The present invention is a tack where the tack itself (not the inserter) includes a spring or other means for varying the effective length thereof. Schutz discloses a rigid tack with no means of varying its length.

Greenberg, the present appellant's prior art, also discloses a spring loaded tacking device (the inserter). The spring is used to rapidly drive the tack into tissue. The spring does not affect the length of the tack. The spring does not remain with the tack once implanted. Figures 1 and 2 cited by the examiner disclose the tack inserter and a rigid tack (reference numeral 6). The Examiner further asserts that reference numeral 5 is a nut to vary the length of the tack. Reference numeral 5 is the tack holder, and is part of the tacking device, not the tack. Further, the shaft (reference numeral 8) is the shaft of the tacking device, not the tack.

Worrich discloses a laparoscopic surgical instrument. The cutting blade of the instrument retracts under a cover by force of a spring like other spring-loaded tools. This helps prevent inadvertent cutting during use of the surgical instrument. No medical tack is disclosed in Worrich, fixed or variable.

In determining the propriety of a rejection under 35 U.S.C. §103, it is well settled that the obviousness of an invention cannot be established by combining the teachings of the prior art absent some teaching, suggestion or incentive supporting the combination. See *In re Fine*, 837 F.2d 1071, 5 USPQ 2d 159 (Fed. Cir. 1988). A test for obviousness is what the combined teachings of the references, taken as a whole, would have suggested to those having ordinary skill in the art. See *In re Kaslow*, 707 F.2d 1366, 217 USPQ 1089 (Fed. Cir. 1983).

During patent examination, the USPTO bears the initial burden of presenting a *prima facie* case of unpatentability. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ 2d 1442 (Fed. Cir. 1992). When the USPTO fails to meet this burden, the applicant is entitled to the patent. However, when a *prima facie* case is made, the burden shifts to the applicant to come forward with evidence and/or argument supporting patentability. Patentability *vel non* is then determined on the entirety of the record, by a preponderance of evidence and weight of argument. See *In re Paisecki*, 745 F.2d 1468, 223 USPQ 785 (Fed. Cir. 1984).

The burden for establishing a *prima facie* case of obviousness thus rests upon the Examiner and can only be satisfied by showing an objective teaching in the prior art or by knowledge generally available to one of ordinary skill in the art that would have led such individual to combine relevant teachings of cited references.

The Examiner's rejection in the present application is based upon the teachings of three references. Two tack inserters, Schutz and Greenberg, and a spring loaded retractor, Wortrich. In the cases of Schutz and Greenberg, the spring's purpose is to insert a tack rapidly to better penetrate tissue. In the cases of Wortrich the spring's purpose is to retract a safety cover. In all three cases, the spring is on a surgical tool rather than an implantable device, such as a tack or nail.

In appellant's preferred embodiment a spring tack is used to attach an electrode array to a retina for artificial visual stimulation, helping blind people see. Appellant has discovered that the thickness of the sclera (eyeball) varies. It is important to apply enough pressure to achieve good electrical contact without squeezing the retina and blocking blood flow. The rigid tack of the prior art is ineffective at achieving this goal. However, a spring mounted hilt allows a tack to adapt to varying scleral thicknesses. As described in the specification there are many applications where it is advantageous to use of medical tack of varying length. Nothing in the prior art even remotely suggests using a spring, or any other means, to vary the length of a tack for accommodating varying tissue thicknesses.

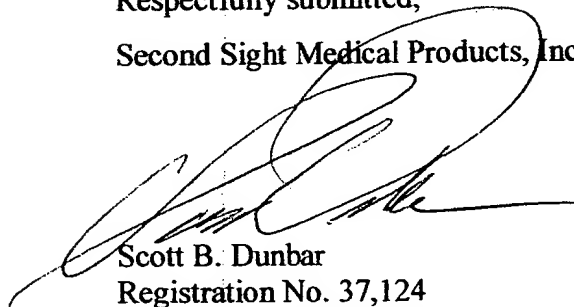
CONCLUSION

Appellant remains convinced that there is simply nothing in the cited references which would have suggested the combination, including the modification required to produce Appellant's claimed subject matter. Appellant further believes that the Examiner has not sustained the burden for establishing and maintaining a *prima facie* case of obviousness, and, therefore, the rejections based on 35 U.S.C. §102 and 103(a) should not stand. The Appellant is convinced that the present claims are patentable and it is

respectfully requested that the final rejection by the Examiner be reversed and the claims allowed.

Respectfully submitted,

Second Sight Medical Products, Inc.

A handwritten signature in black ink, appearing to read 'Scott B. Dunbar', is written over the company name.

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APPENDIX A
Claims Under Appeal

1. A medical tack comprising:
a shaft having a point end and a base end;
an attachment point formed near said point end;
an attachment point formed near said base end; and
means for varying a position of one of said attachment points.
2. The medical tack according to claim 1, wherein said means for varying said position is a nut.
3. The medical tack according to claim 1, wherein said means for varying said position is an elastomer.
4. The medical tack according to claim 1, wherein said means for varying said position is a spring.
5. The medical tack according to claim 4, further comprising a flange near said base end for seating said spring.
6. The medical tack according to claim 5, wherein said spring is a coil spring formed around said shaft.
7. The medical tack according to claim 4, wherein said spring is a dome spring.
8. The medical tack according to claim 4, wherein said spring is a leaf spring.

9. The medical tack according to claim 4, wherein said spring is a plurality of leaf springs of varying length.

10. The medical tack according to claim 6, further comprising a washer adjacent to said spring.

11. A retinal tack for attaching a retinal device comprising:
a shaft having a point end and a base end;
an attachment point formed near said point end;
an attachment point formed near said base end; and
means for varying a position of one of said attachment points.

12. The retinal tack according to claim 11, wherein said means for varying said attachment point is a nut.

13. The retinal tack according to claim 11, wherein said means for varying said attachment point is a spring.

14. The retinal tack according to claim 11, wherein said shaft is sized such that said tack will pierce said retinal device, a retina and a sclera such that said attachment point formed near said point end abuts a back side of the sclera and tends to prevent the tack from being withdrawn.

15. The retinal tack according to claim 13, further comprising a flange near said base end for seating said spring.

16. The retinal tack according to claim 13, wherein said spring is a coil spring formed around said shaft.

17. The retinal tack according to claim 13, wherein said spring is a dome spring.

18. The retinal tack according to claim 13, wherein said spring is a leaf spring.

19. The retinal tack according to claim 13, wherein said spring is a plurality of leaf springs of varying length.

20. The retinal tack according to claim 16, further comprising a washer adjacent to said spring.

21. The retinal tack according to claim 13, wherein said spring exerts less than 0.2 g/mm^2 across the surface of a retinal device.

22. A retinal tack for attaching a retinal device comprising:
a shaft having a point end and a base end;
a barb formed near said point end;
a flange formed near said base end;
a coil spring, having one end affixed to said flange and circling around said shaft;
and
a washer affixed to an end of said spring, opposite to said one end, wherein said shaft is sized such that said tack will pierce said retinal device, a retina and a sclera such that said barb abuts a back side of the sclera and tends to prevent the tack from being withdrawn, and said washer abuts said retinal device exerting less than 0.2 g/mm^2 across the surface of a retinal device.